Ocular Therapeutix™ and Regeneron Enter Into Strategic Collaboration to Develop Sustained Release Formulation of Aflibercept for the Treatment of Wet AMD and Other Serious Retinal Diseases

October 13, 2016

Sustained Release Formulation Has Potential to Significantly Advance Current Standard of Care by Reducing Injection Frequency in the Treatment of Wet AMD

Ocular Therapeutix Eligible to Receive up to $305 Million in Milestone Payments in Addition to Royalties on Potential Future Net Sales

Company to Host Conference Call Today at 8:30 am Eastern Time

BEDFORD, Mass--(BUSINESS WIRE)--Oct. 13, 2016-- Ocular Therapeutix, Inc. (NASDAQ: OCUL), a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye, today announced that it has entered into a strategic collaboration, option and license agreement with Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN). Ocular and Regeneron will collaborate on the development of a sustained release formulation of the vascular endothelial growth factor (VEGF) trap aflibercept for the treatment of wet age-related macular degeneration (wet AMD) and other serious retinal diseases. This formulation is currently in preclinical development. Regeneron's aflibercept is currently approved by the U.S. Food and Drug Administration for certain indications under the brand name EYLEA®.

Ocular Therapeutix is currently developing proprietary sustained-release hydrogel-based drug delivery depots for intravitreal injection that can be formulated with both small and large molecule pharmaceuticals, such as tyrosine kinase inhibitors (TKIs) and protein-based anti-VEGFs, respectively, with the goal of delivering sustained and therapeutic levels of drugs to targeted ocular tissues.

Under the terms of the agreement, Ocular Therapeutix and Regeneron will aim to develop a sustained release formulation of aflibercept that is suitable for advancement into clinical development. Regeneron has the option to obtain an exclusive license to use Ocular Therapeutix's hydrogel-based technology for the development and commercialization of a sustained release formulation of aflibercept and other biologics targeting VEGF for ophthalmic indications. Ocular Therapeutix will retain all rights to develop its sustained-release hydrogel-based drug delivery platform with all other non-VEGF targeting compounds as well as with small molecule pharmaceuticals, including TKIs, for other retinal diseases.

Upon exercising of the option, Ocular Therapeutix would receive a payment of $10 million from Regeneron and Ocular Therapeutix would be responsible for funding development through Phase 1. Regeneron would be responsible for any subsequent development and commercialization costs. Ocular Therapeutix would be eligible to receive up to $305 million in milestone payments from Regeneron for a sustained release version of aflibercept containing Ocular Therapeutix's sustained release hydrogel depot, comprised of up to $155 million in development and regulatory milestone payments, $100 million for the first commercial sale and up to $50 million in commercial milestone payments. In addition, Ocular Therapeutix is eligible to receive tiered high single-digit to low-to-mid teen-digit royalties on potential future net sales.

"We have made considerable progress in developing our protein drug delivery platform at Ocular Therapeutix, so it is good to see an industry leader such as Regeneron recognizing the potential of this technology," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman of Ocular Therapeutix. "We are excited to partner with Regeneron to develop a potential first-in-class sustained release protein-based anti-VEGF hydrogel injection for wet AMD, DME, RVO, and other serious retinal diseases. This sustained release formulation could have the potential to significantly reduce dosing frequency and subsequently reduce doctor visits, thus reducing the burden of care for patients, caregivers and physicians, and may decrease the likelihood of certain side effects associated with frequent intravitreal injections."

About Wet AMD and Other VEGF-Associated Retinal Diseases

Wet age-related macular degeneration (wet AMD) is characterized by loss of vision caused by degeneration of the central portion of the retina. Abnormal growth of blood vessels below the retina, and the leakage of fluid and protein from the vessels, causes retinal degeneration and can lead to severe and rapid loss of vision. Wet AMD is the leading cause of blindness in individuals aged 50 years or older.

Retinal vein occlusion (RVO) is a sight-threatening disorder resulting from the blockage of one of the veins carrying blood out of the retina. In RVO, the blockage of a retinal vein can lead to poor blood circulation, low oxygen and sometimes inflammation in the eye. A blocked vein will leak its contents of blood and fluid. Bleeding within the retina and swelling from the fluid can result in macular edema.

Diabetic macular edema (DME) is a complication of diabetes caused by fluid accumulation in the macula, or central portion of the eye. When the macula begins to fill with fluid, the ability of those cells to sense light is impaired, causing blurred vision that can be severe. Diabetic macular edema affects up to 30% of people who have had diabetes for 20 years or more, and if untreated, 20 to 30% of people who have it will experience moderate visual loss.

The global market for anti-VEGF drugs is over $7.5 billion.

Conference Call & Webcast Information

Members of the Ocular Therapeutix management team will host a live conference call and webcast today at 8:30 am Eastern Time to discuss the collaboration with Regeneron as well as other recent progress from the Company's intravitreal depot development programs.

The live webcast and accompanying slide presentation can be accessed by visiting the investor section of the Company's website at investors.ocutx.com. Please connect at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call 844-464-3934 (U.S.) or 765-507-2620 (International) to listen to the conference call. The conference ID number for the live call will be 98223266. An archive of the webcast will be available until October 27, 2016 on the Company's website.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. (NASDAQ: OCUL) is a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary hydrogel platform technology. Ocular Therapeutix has submitted an NDA for post-surgical pain for its lead product candidate, DEXTENZA™ (dexamethasone insert, extended release), which is in Phase 3 clinical development for post-surgical ocular inflammation and pain and allergic conjunctivitis, and in Phase 2 clinical development for dry eye disease. OTX-TP (sustained release travoprost) is in Phase 3 clinical development for glaucoma and ocular hypertension. Ocular Therapeutix is also evaluating sustained-release injectable drug depots for back-of-the-eye diseases. Ocular Therapeutix's first product, ReSure® Sealant, is FDA-approved to seal corneal incisions following cataract surgery. For additional information about the Company, please visit www.ocutx.com.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the potential benefits and future operation of the collaboration with Regeneron, including any potential future payments thereunder, the ongoing development of the Company's sustained release hydrogel depot technology, the development and regulatory status of the Company's other product candidates, such as the Company's expectations and plans regarding regulatory submissions for and the timing and conduct of clinical trials of DEXTENZA™ for post-surgical ocular inflammation and pain, including our expectations regarding the NDA filed with the FDA, DEXTENZA for the treatment of allergic conjunctivitis, DEXTENZA for dry eye disease and OTX-TP for the treatment of glaucoma and ocular hypertension, the potential utility of any of the Company's product candidates, potential commercialization of the Company's product candidates, the sufficiency of the Company's cash resources and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "may", "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to the timing and costs involved in commercializing ReSure® Sealant or any product candidate that receives regulatory approval, the initiation and conduct of clinical trials, availability of data from clinical trials and expectations for regulatory submissions and approvals, the Company's scientific approach and general development progress, the availability or commercial potential of the Company's product candidates, the sufficiency of cash resources and need for additional financing or other actions and other factors discussed in the "Risk Factors" section contained in the Company's quarterly and annual reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this release. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this release.

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